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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/405,050 | 09/27/1999 | YEHUDA SHOENFELD | ZAP-1CIPCONC | 9070 |

7590 05/17/2006

JANE A MASSARO
FISH & NEAVE
1251 AVENUE OF THE AMERICAS
NEW YORK, NY 10020

EXAMINER

NAVARRO, ALBERT MARK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1645

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,050

Applicant(s)

SHOENFELD ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 22-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on April 26, 2006 has been entered.

Accordingly claims 1-11 and 22-29 remain pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1-11 and 22-29 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a new matter rejection is maintained.

Applicants are asserting that there is no distinction between subpopulations with "active" or "passive" metastasis, instead once metastasis has occurred, it is by its nature active. Applicants further assert that support for the use of a preparation of IVIG for treating metastastatic lymphoma in a mammal does not rely solely on Examples 1-5, but also on Example 8, which clearly demonstrated that lymphoma cells are responsive to

IVIG, inhibiting cell proliferation. Applicants further assert that several metastatic cell biomarkers exist, that are the same across various cancer origins such as melanoma, sarcoma and lymphoma, and consequently there could be a common treatment that would be effective in treating cancer of several types.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are asserting that there is no distinction between subpopulations with “active” or “passive” metastasis, instead once metastasis has occurred, it is by its nature active. However, Applicants are respectfully directed back to their claim language, which recites “wherein the mammal has metastatic lymphoma.” Applicants specification sets forth of therapeutic methods for “inhibiting tumor metastasis.” (Page 3, lines 15-17). One of skill in the art could readily practice such an invention by administering IVIG to any patient with a lymphoma, and indeed this has been done by those of skill in the art, e.g., Chapel et al of record. However, that rejection was specifically withdrawn in view of Applicants amendment to recite “wherein the mammal has metastatic lymphoma.” One of skill in the art would then be required to detect more than just a lymphoma in a patient prior to administering IVIG, one would additionally need to determine if the detected lymphoma had metastasized to a secondary site, and then, and only then administer IVIG, it is this key limitation which is silent in Applicants specification.

Second, Applicants assert that support for the use of a preparation of IVIG for treating metastastatic lymphoma in a mammal does not rely solely on Examples 1-5, but

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also on Example 8, which clearly demonstrated that lymphoma cells are responsive to IVIG, inhibiting cell proliferation. However, once again, Example 8 was carried out in vitro. No determination of metastasis was made, nor could have possibly been made in vitro.

Finally, Applicants assert that several metastatic cell biomarkers exist, that are the same across various cancer origins such as melanoma, sarcoma and lymphoma, and consequently there could be a common treatment that would be effective in treating cancer of several types. However, Applicants appear to be overlooking several features which are not shared by the different types of cancer. For instance, lymphomas and carcinomas metastasize via different routes, i.e., lymphatic system vs. circulatory system. Furthermore, lymphomas and sarcomas are treated very differently by those of ordinary skill in the art (MDs). Lymphomas are responsive to chemotherapy, less responsive to radiation therapy, while sarcomas are much more responsive to radiation therapy. (See meb.uni-bonn.de/cancer.gov/CDR0000062710 and meb.uni-bonn.de/cancer.gov/CDR0000257991).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Double Patenting

2. The rejection of claims 1-11 and 22-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,965,130 is maintained.

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It is noted that Applicants have indicated a willingness to submit a terminal disclaimer upon an indication that all other rejections are withdrawn. However, until a terminal disclaimer is made of record, this rejection is maintained for reasons of record.

3. The rejection of claims 1-11 and 22-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,562,902 is maintained.

It is noted that Applicants have indicated a willingness to submit a terminal disclaimer upon an indication that all other rejections are withdrawn. However, until a terminal disclaimer is made of record, this rejection is maintained for reasons of record.

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
May 14, 2006